K093090

510(k) Summary

for

DEC 17 2009

GALILEOS Implant V1.7

1 Company Name and Address

1.1 Sponsor

SICAT GmbH & Co. KG
Brunnenallee 6
D-53177 Bonn
Germany

Manufacturer

SICAT GmbH & Co. KG
Brunnenallee 6
D-53177 Bonn
Germany
Registration Number: 3006098230
Operations: Manufacturer
Status: Active

1.2 Contact

SICAT GmbH & Co. KG
Brunnenallee 6
D-53177 Bonn
Germany

Telephone: +49-228/854 697 84
Facsimile: +49-228/854 697 99

Primary Contact: Mr. Markus Pfister
Secondary Contact: Mr. Dr. Manfred Breuer

2 Device Name and Classification

Proprietary Name:	GALILEOS Implant
Common/Usual Name:	Preoperative Dental Implant Planning Software
Classification Name:	System, Image Processing, Radiological
Regulation Description:	Picture archiving and communications system

Product Code:	LLZ
Regulation Number:	892.2050
Classification Class:	Class II Product

3 Predicate Device

GALILEOS Implant V1.7 is claimed to be substantially equivalent in material, design and function to the SimPlant 12 product which was cleared by FDA under 510(k) K033849 (May 25, 2004), K053592 (Feb 8, 2006), K081402 (JUL 18, 2008) and the GALILEOS Implant V1.0 product which was cleared by FDA under 510(k) K061472 on June 9, 2006.

4 Device Description

GALILEOS Implant V1.7 is a pure software device.

GALILEOS Implant V1.7 is a planning and simulation software to aid qualified dental professionals in the placement of dental implants and the planning of surgical implant treatments. GALILEOS Implant is based on medical imaging information presented by the Sirona GALAXIS 3D viewer and produced by Sirona GALILEOS medical cone beam scanner.

GALILEOS Implant V1.7 allows to name, position, move, rotate, resize and visualize dental implants and other planning objects (i.e. nerve canals) within the visualized 3D volume. Thus, dental professionals like implantologists are enabled to precisely plan the positions, orientations, types and sizes of implants to be placed in the patient's mandible/maxilla together with the related surgical procedures.

The dental professionals' planning data may be exported from GALILEOS Implant V1.7 and used as input data for CAD (Computer-Aided Design) or Rapid Prototyping Systems.

5 Intended Use

GALILEOS Implant V1.7 is intended for use as planning and simulation software to aid qualified dental professionals in the placement of dental implants and the planning of surgical implant treatments. GALILEOS Implant is based on medical imaging information presented by the Sirona GALAXIS 3D viewer and produced by Sirona GALILEOS medical cone beam scanner. The dental professionals' input information may be exported from GALILEOS Implant and used as input data for CAD (Computer-Aided Design) or Rapid Prototyping Systems.

6 Substantial Equivalence

The GALILEOS Implant V1.7 system is substantially equivalent to the SimPlant 12 System (K033849, K053592, K081402) and the GALILEOS Implant V1.0 System (K061472) based on the equivalence of the intended use, similar features and technical characteristics. Performance testing to validate the safety and effectiveness of the GALILEOS Implant V1.7 system included validation testing and bench tests of the software functions.

7 Conclusion

GALILEOS Implant V1.7 is considered to be substantially equivalent in design, material and function to the SimPlant 12 System and the GALILEOS Implant V1.0 System.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SICAT GmbH & Co. KG
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

DEC 17 2009

Re: K093090
Trade/Device Name: GALILEOS Implant V1.7
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 1, 2009
Received: December 4, 2009

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1 INDICATIONS FOR USE STATEMENT

for
GALILEOS Implant V1.7

510(k) Number (if known): K093090

Device Name: GALILEOS Implant V1.7

Indications for Use:

GALILEOS Implant is intended for use as planning and simulation software to aid qualified dental professionals in the placement of dental implants and the planning of surgical implant treatments. GALILEOS Implant is based on medical imaging information presented by the Sirona GALAXIS 3D viewer and produced by Sirona GALILEOS medical cone beam scanner. The dental professionals' input information may be exported from GALILEOS Implant and used as input data for CAD (Computer-Aided Design) or Rapid Prototyping Systems.

Prescription Use X (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093090